

OMB# 0910-0810
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INFORMED CONSENT FORM

LGBT Campaign: Wave 1B Online Quantitative Study Designed to Prevent Young Adult Tobacco Use

Sponsor: U.S. Food and Drug Administration's
Center for Tobacco Products

Principal Investigator: Mayo Djakaria, MPH

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Please read this form carefully. You can contact the PI of this study at the above email address or phone number. You can ask as many questions as you want. Any question you may have needs to be addressed before you submit this form.

Introduction: About this study

The purpose of this research is to determine whether video ads designed to prevent lesbian, gay, bisexual, and transgender (LGBT) young adults ages 18 to 24 from using tobacco are understandable and engaging.

Rescue Social Change Group (Rescue) is a health communications and research company. We are working with the U.S. Food and Drug Administration's Center for Tobacco Products to conduct a study with LGBT young adults ages 18 to 24. The study will show draft versions of video ads. We will then try to learn if the messages are understood. We also want to know if you think the video ad is understandable and engaging.

What will I do during this study?

You will be one in a group of 1,050 LGBT young adults participating in this study. The study will take up to 19 minutes to complete, including the screener survey that you completed. Some participants will view 1 video ad. Others will not view an ad. Whether or not you see the video ad is randomly assigned. If you see the video ad, it will be close to the final version that still needs small edits. You will complete a survey to help make the video ad final.

You may be asked to view 1 video ad and tell us your opinion about it. If you are not shown an ad, the study will take no longer than 11 minutes to complete including the screener survey that you completed. Additionally, you will be asked questions related to tobacco use and your attitudes about tobacco. We may collect information you provide from both the screener and the study survey.

You can choose to take part in the study or not. You can choose to stop taking the survey at any time.

Privacy: Who will see the information I provide during this study?

We will take care to protect your privacy. The survey will be on a secure website that is password protected. Your answers will be kept private to the extent allowable by law. That means we will not share your answers with anyone outside the study unless it is necessary to protect you, or if required by law. The answers you provided earlier, which include gender, age, race, and ethnicity, will be used for study analysis but will not be connected to your personal information such as zip code, email, or IP address. The research team may contact you about the Survey using the contact information you provide (your email address). The research team will not use your contact information for any other purpose than contacting you about the survey or delivering your incentive. **Your contact information will not be shared with others.**

De-identified findings from this study, including sample descriptions, may appear in professional journals or at scientific conferences. We will not disclose your identity in any report or presentation.

We will keep the answers you provide for three years after the study is complete on a password-protected computer. Three years after the study is complete, we will destroy all of the data by permanently deleting records.

Study Benefits: What good will come from this study?

This study is not expected to directly benefit you. However, your answers will help us determine whether video ads about the harms of tobacco use are understandable and engaging and may prevent tobacco use amongst LGBT young adults.

Anticipated Risks: Could anything bad happen to me during this study?

We will take care to protect the data you provide. However, as with all studies, there is a chance that privacy could be broken by accident or the result of hacking. In the unlikely event that this study data is hacked we will inform you within 5 business days of discovery. We will try our best to maintain the privacy of data collected during the study by providing standard online data safeguards.

All video ads will be presented in the context of tobacco use prevention. If you have any questions about tobacco use or prevention, you can ask a health care professional or your local health department. If you have any questions about this research study, you may call or email the Principal Investigator at the telephone number or email address listed on this form.

Remember that you can stop participating in this study at any time.

Will I be paid for being in this study?

Everyone who completes and submits this survey will receive a \$15 online gift card via email within 72 hours of submitting the survey as a thank you for your time.

All participants must fully complete the study questionnaire to receive the incentive. The survey may only be submitted once and participants will only receive one \$15 online gift card incentive.

Participation and Withdrawal: Do I have to be in this study? What if I want to drop out?

Your participation in this study is completely voluntary. You can choose to take part in the study or not, regardless of what other participants choose to do. You can choose to stop taking the study survey at any time. You do not have to answer any questions you do not want to. Participants who willingly choose not to complete the study survey will not receive the \$15 online gift card incentive. You will receive the \$15 online gift card incentive upon completion and submission of the study questionnaire.

Questions and Contacts: Who do I call if I have questions now or later?

If you have any questions about this study, you may call Mayo Djakaria at Rescue or Dana Wagner at Rescue (619-231-7555 x 153) or info@lgbtculturesurvey.com. The Research Involving Human Subjects Committee (RIHSC) at the Food and Drug Administration has reviewed this research. RIHSC is an institutional review board (IRB), a group of people who are responsible for ensuring that the rights of participants in research are protected. The RIHSC is not involved in this study but may review the records of your participation in this research to ensure that proper procedures were followed. If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact RIHSC at 301-796-9605 or RIHSC@fda.hhs.gov.

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 5 minutes per response to review this informed consent form (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.